



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,754	02/08/2001	Jeffrey E. Stahmann	279.380US1	5548

7590

10/16/2002

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402

EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3751

DATE MAILED: 10/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,754

Applicant(s)

STAHMANN ET AL.

Examiner

Anu Ramana

Art Unit

3751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 41-56 is/are rejected.
- 7) ☒ Claim(s) 41,43-48, 50-54 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Elections/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-40, drawn to an apparatus, classified in class 607, subclass 9.
- II. Claims 41-56, drawn to a method, classified in class 607, subclass 15.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case process can be practiced by a different apparatus, such as one that does not have a right ventricular electrode but has a supraventricular electrode.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Suneel Arora on September 26, 2002, a provisional election was made without traverse to prosecute the invention of Group II, claims 41-56. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "207" and "235" have both been used to designate the same part. Reference characters "236" and "238" are not clearly marked in Figure 2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference elements not mentioned in the description: 300', 302', 304', 306' (see Figure 3). In Figure 10, it appears that "CHESS" should be "CROSS."

A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because it must be restricted to the elected invention. Correction is required.

The disclosure is objected to because of the following informalities.

It appears that "bipolar" has been misspelled as "biopolar" (for e.g. page 5, line 29). Applicant should check the disclosure carefully and correct minor typographical errors.

Claim Objections

Claims 41, 43-48, 50-54 are objected to because of the following informalities.

Claims 41, 43-44, 47-48, 50-51 and 54 are objected to because of the phrase "pulses vector" which should be "pulse vectors" to be consistent with the disclosure.

Claim 45, 46, 52 and 53 are further objected to because of the confusing term "common." It appears that "common" implies same polarity and appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 41, 42, 44, 48, 49 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Alt et al.

Alt et al. disclose a first left ventricular electrode 73 for pacing and sensing, a second left ventricular electrode 77 and a right ventricular electrode 67 (Figure 4) for simultaneous pacing of the right and left ventricles of a patient's heart (col. 3, lines 23-26, lines 32-39, and lines 65-67; col. 4, line 1; col. 5, lines 27-42; and col. 12, lines 52-58). Alt et al. also disclose a device 10 with a function generator 16 for therapy-generating and delivery functions wherein the functions may be varied by programming (col. 7, lines 33-63).

Alt et al. further disclose a right atrial or supraventricular electrode 63 (Figure 4) for pacing stimulation in various modes (col. 3, lines 32-39; col. 5, lines 37-42; col. 10, lines 8-17; col. 13, lines 30-37).

The method steps of claims 41, 42, 44, 48, 49 and 51 are inherently performed by the device 10 of Alt et al. during normal use in various modes of operation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. in view of Stoop et al.

Alt et al. disclose that the metal housing (case or can) 11 (Figure 3) of device 10 can be used as an active electrode for any particular type of therapy (col. 3, lines 22-26 and col. 7, lines 43-48). See previous discussion for claims 41 and 48.

Attention is directed to Stoop et al. that teach unipolar pacing of a heart chamber (right or left ventricle) by delivering pacing pulses from a pulse generator 15 between a first ventricular electrode 16T and the pacemaker can or housing 8 (Figure 1, col. 1, lines 38-46 and col. 2, lines 29-32, lines 40-53 and lines 56-65).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have programmed pacing pulses between a right ventricular electrode or a left ventricular electrode and the conductive housing 11 of Alt et. al as taught by Stoop et al. for unipolar pacing of the right or left ventricle.

The method steps of claims 43 and 50 are rendered obvious by the above discussion.

Claims 45, 46, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. in view of Smits.

Alt et al. disclose that the metal housing (case or can) 11 (Figure 3) of device 10 can be used as an active electrode for any particular type of therapy (col. 3, lines 22-26 and col. 7, lines 43-48). Alt et al. do not specifically disclose that a pacing pulse is delivered from the first and second left ventricular electrodes in common to the first right ventricular or supraventricular electrode. See previous discussion for claims 41, 44, 48 and 51.

Smits teaches two ventricular electrodes 240 and 242 mounted on the left ventricle and a third electrode 244 mounted on the right ventricle wherein electrodes 240 and 242 have like polarity and electrode 244 has an opposite polarity for the delivery of a bipolar pulse regime (col. 9, lines 50-66).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have delivered a bipolar pulse regime as taught by Smits between

Art Unit: 3751

electrodes 73 and 77 and electrodes 64 or 67 of Alt et al. by making electrodes 73 and 77 of like polarity (common) and electrodes 64 or 67 of opposite polarity.

The method steps of claims 45, 46, 52 and 53 are rendered obvious by the above discussion.

Claims 47 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. in view of Speicher et al.

Alt et al. do not disclose a third left ventricular electrode.

Speicher et al. teach the use of multiple electrodes on a unitary intravascular catheter wherein a distal electrode 10 is used for sensing and pacing, an intermediate electrode 18 is used for sensing and cardioverting and a proximal electrode 48 is used for sensing and cardioverting (Figure 1, col. 3, lines 53-55, col. 4, lines 57-61, col. 6, lines 64-68 and col. 7, lines 1-8).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a first distal, a second intermediate and a third proximal electrode as taught by Speicher et al. in the device 10 of Alt et al. for pacing, sensing and cardioverting. See previous discussion for claims 41 and 48.

The method steps of claims 47 and 54 are rendered obvious by the above discussion.

Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. in view of Thong et al.

Alt et al. disclose a first ventricular defibrillation electrode 70 and a distal pacing/sensing electrode 67 at apex 69 of the right ventricular region (Figure 4, col. 9, lines 59-67 and col. 10, lines 1-7).

Alt et al. do not disclose delivering a pacing pulse from electrode 70 as a cathode to electrode 67 as an anode.

Thong et al. teach a ventricular bipolar lead 12 having cathodic and anodic electrodes for tripolar stimulation in the right ventricle (col. 5, lines 3-4 and lines 24-28).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided electrode 70 as a cathode and electrode 67 as an anode as taught by Thong et al. for tripolar cardiac stimulation in the right ventricle.

The method steps of claims 55 and 56 are rendered obvious by the above discussion.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached on 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0975.

AR
October 15, 2002



**TIMOTHY L. MAUST
PRIMARY EXAMINER**